DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
94371d
Central Region

Food and Drug Administrat
Waterview Corporate Cent
10 Waterview Blvd., 3rd Fl
Parsippany, NJ 07054

Telephone (973) 526-6010

October 22, 2003

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER

Ms. Nancy Mercandante
Acting President
Cares Built, Inc.
75 Manchester Avenue
Keyport, New Jersey 07735

04-NWJ-03

Dear Ms. Mercandante:

During an inspection of your establishment located in Keyport, NJ, on September 9-11 & 15, 2003, our investigator determined that your establishment manufactures remote switches for portable X-Ray machines and acts as an own label distributor for radiography and fluoroscopy equipment. Radiography, fluoroscopy, and X-Ray equipment are devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

The above-stated inspection revealed that these devices are adulterated within the meaning of Section 501(h) of the Act, in that the methods used in, or the facilities or controls used for manufacturing, packing, storage, or installation are not in conformance with the Quality System regulation for medical devices, as specified in Title 21, Code of Federal Regulations (21 CFR), Part 820, as follows:

1. Management failed to establish a quality policy and objectives for, and commitment to, quality as required by 21CFR 820.20. In addition, your firm failed to appointment a Quality System management representative, and failed to periodically conduct a management review to evaluate the suitability and effectiveness of the quality system.
2. Failure to establish a quality plan to define the quality practices, resources, and activities that are relevant to devices (21CFR820.20(d)).
3. Failure to conduct quality audits, and failure to establish procedures for conducting quality audits as required by 21 CFR 820.22.

4. Failure to establish and maintain design control procedures as required by 21CFR 820.30. Specifically, for the Clarity 7000 device, no procedures were established for design input or output, design changes, design verification and validation, etc. Furthermore, no design history file was established for the Clarity 7000 device (21 CFR 820.30(j)).
5. Failure to establish and maintain procedures for implementing corrective and preventive action as required by 21CFR 820.100.
6. Failure to establish and maintain procedures for receiving, reviewing and evaluating complaints and ensuring the complaints are handled in a timely manner (21CFR 820.198).
7. Failure to establish and maintain procedures to ensure that purchased or otherwise received products and services conform to specified requirements. Specifically, the manufacture of equipment, such as the Athena, Apollo, and Atlas devices and the Raymote III portable X-Ray switch, is all outsourced to contract manufacturers. There are no procedures in place to evaluate the contract manufacturers or their ability to meet specified requirements (21CFR 820.50).
8. Failure to implement written Medical Device Report (MDR) procedures as required by 21CFR 803.17.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and on the Form FDA-483, issued at the conclusion of the inspection, may be symptomatic of serious underlying problems in your establishment's quality system. You are responsible for investigating and determining the causes of the violations found by the FDA. You also must promptly initiate permanent corrective and preventive action on your Quality System.

We have received your response which was emailed directly to our investigator, dated September 29, 2003. The response is not adequate in that it does not address any of the specific observations or any specific actions you will be taking in order to correct the observations.

Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts. Additionally, no premarket submissions for Class III devices to which the Quality System/GMP deficiencies are reasonably related will be cleared or approved until the violations have been corrected. Also, no requests for Certificates to Foreign Governments will be approved until the violations related to the subject devices have been corrected.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

Please notify this office within 15 working days of receipt of this letter of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to identify and make corrections to any underlying systems problems necessary to assure that similar violations will not recur. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be implemented.

Your response should be sent to Sarah A. Della Fave, Compliance Officer, U.S. Food and Drug Administration, New Jersey District, 10 Waterview Boulevard, 3rd Floor, Parsippany, NJ 07054,

Sincerely,

Diana Amador-Toro for
Douglas I. Ellsworth
District Director
New Jersey District

cc: Mr. James Ferrell
Vice President of Operations
Cares Built, Inc.